Complete Summary

GUIDELINE TITLE

Care of the contact lens patient.

BIBLIOGRAPHIC SOURCE(S)

American Optometric Association. Care of the contact lens patient. St. Louis (MO): American Optometric Association; 2000 Jan 1. 77 p. (Optometric clinical practice guideline; no. 19). [178 references]

GUI DELI NE STATUS

This is the current release of the guideline.

According to the guideline developer, this guideline has been reviewed on a biannual basis and is considered to be current. This review process involves updated literature searches of electronic databases and expert panel review of new evidence that has emerged since the original publication date.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

On April 7, 2005, after concluding that the overall risk versus benefit profile is unfavorable, the FDA requested that Pfizer, Inc voluntarily withdraw Bextra (valdecoxib) from the market. The FDA also asked manufacturers of all marketed prescription nonsteroidal anti-inflammatory drugs (NSAIDs), including Celebrex (celecoxib), a COX-2 selective NSAID, to revise the labeling (package insert) for their products to include a boxed warning and a Medication Guide. Finally, FDA asked manufacturers of non-prescription (over the counter [OTC]) NSAIDs to revise their labeling to include more specific information about the potential gastrointestinal (GI) and cardiovascular (CV) risks, and information to assist consumers in the safe use of the drug. See the <u>FDA Web site</u> for more information.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **
SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS QUALIFYING STATEMENTS IMPLEMENTATION OF THE GUIDELINE INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

- Refractive errors (anisometropia, myopia, hyperopia, presbyopia, regular astigmatism)
- Aphakia
- Keratoconus
- Corneal irregularity secondary to trauma, disease, surgery
- Accommodative esotropia or convergence excess

GUIDELINE CATEGORY

Diagnosis Evaluation Management Treatment

CLINICAL SPECIALTY

Optometry

INTENDED USERS

Health Plans Optometrists

GUI DELI NE OBJECTI VE(S)

- To identify patients who might benefit from contact lens wear
- To evaluate patients who wear, or who desire to wear, contact lenses
- To maintain and improve the care of patients wearing contact lenses
- To manage complications encountered during contact lens wear
- To inform and educate other health care practitioners as well as the lay public about contact lens care
- To assist in the professional care of patients wearing contact lenses

TARGET POPULATION

Contact lens wearers

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Pre-fitting indications, including:
 - Evaluation of patient's suitability for contact lens use, including indications and cautions
 - Types of contact lenses (hydrogel, rigid, hybrid, and silicone)
- 2. Contact lens examination and fitting, including:
 - Fitting for different types of contact lenses
 - Determination of optical power
 - Special design features (lenticular edge modifications; prism and truncation; fenestrations; blending)
 - Special concerns for presbyopia, dry eye and extended wear
- 3. Patient education
- 4. Follow-up evaluation
- 5. Management of complications

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches using the National Library of Medicine's Medline database and the VisionNet database.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not applicable

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The Reference Guide for Clinicians was reviewed by the American Optometric Association (AOA) Clinical Guidelines Coordinating Committee and approved by the AOA Board of Trustees.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Excerpted by the National Guideline Clearinghouse (NGC)

Care Process

A. Pre-Fitting Considerations

Many factors help determine whether a patient is a good candidate for contact lenses. Primary among these is motivation to be a successful contact lens wearer. Unfortunately, there is no individual test or battery of tests that can predict success in wearing contact lenses.

1. Indications

Some factors that suggest whether a patient is a good candidate for contact lens wear involve optical, physiologic, and cosmetic considerations. The following indications should be considered in the evaluation of a patient's potential for successful contact lens use (See also Table 1 in the original guideline).

a. Optical Factors

Contact lenses improve visual function by neutralizing ametropia, or minimizing distortion, especially when the patient suffers from more than a modest spherical refractive error or astigmatism, regular or irregular. Myopic patients benefit from the increased magnification provided by contact lenses, compared with their spectacle corrections. The reverse is true for both hyperopic and aphakic patients; however, such patients benefit from enhanced fields of vision with contact lenses. For anisometropic patients, aniseikonia and prismatic effects may be reduced or eliminated with contact lens wear.

b. Presbyopia

Although many patients with presbyopia wear contact lenses, presbyopia is not specifically an indication for contact lens correction. Presbyopic patients may wear distance contact lenses and use additional reading spectacles of various types to address their presbyopia. Alternatively, presbyopes (especially emerging presbyopes) often successfully use what has been termed "monovision" correction in which one eye wears a contact lens to correct for distance vision and the other wears a contact lens to correct for near vision. Various bifocal contact lenses are available in either rigid gas permeable or hydrogel materials.

c. Therapeutic Potential

Contact lenses have been used to manage both aphakia and binocular vision problems, especially accommodative esotropia and convergence excess. Contact lenses, particularly rigid contact lenses, can optically smooth an anterior corneal surface made irregular by disease (e.g., keratoconus or corneal microbial infection), trauma, or surgery (e.g., penetrating keratoplasty or ineffective refractive surgery). Hydrogel lenses are used as ophthalmic bandages following corneal trauma or refractive corneal surgery. Rigid contact lenses also have been used to manage or reduce myopia. Both clear and tinted rigid and soft contact lenses have been used for treatment by occlusion in cases of diplopia and amblyopia.

d. Cosmetic Effect

Correcting ametropia by placing a lens directly on the corneal surface improves cosmesis by eliminating the need for a spectacle frame and often unattractive corrective ophthalmic lenses. Some patients elect to wear colored contact lenses simply to change the appearance of their eye color. Opaque contact lenses also may be used for their prosthetic effect (e.g., masking an unattractive corneal scar or damaged iris or providing an artificial pupil in the treatment of aniridia).

2. Cautions

Any patient whose clinical situation suggests increased risk of ocular infection or inflammation, but who insists on cosmetic contact lens fitting, should give formal informed consent before the clinician provides contact lenses. Several factors could limit a patient's suitability for contact lens wear, as discussed below (See also Table 2 in the original guideline).

a. Ocular Considerations

Cosmetic contact lens wear should be approached cautiously with patients who present with any active anterior segment disease, especially ocular (or adnexal) inflammation, infection, or severe dry eye conditions, because of the possible increased risk of complications, especially corneal neovascularization or infection. Such diseases include acne rosacea, Sjögren syndrome, atopic dermatitis, corneal exposure, severe blepharitis, conjunctival cicatrizing disorders, neurotrophic keratitis, dacryocystitis, and patent filtering blebs. Therapeutic contact lenses are occasionally used as bandages, however, in these and other disease states.

Placing the lens directly in the precorneal tear film increases the risk of tissue compromise. Contact lens use should therefore be approached cautiously for either the monocular patient (because of risk to the patient's only useful eye) or for the patient who is engaged in an avocation or vocation with exposure to a particularly dirty or dry environment. Such individuals may be advised to wear protective spectacles.

A mildly abnormal tear layer, whether insufficient in volume or of poor quality, decreases the likelihood of successful and asymptomatic contact lens wear, but contact lenses should be considered in the context of patient motivation and other relevant indications. Some forms of abnormal tear layers can be treated with supplemental artificial tear drops or ointments and mechanical or thermal occlusion of the nasolacrimal punctae (See "Dry Eye" under "Care Process-Contact Lens Examination and Fitting-Special Concerns" [Section IIB4b] in the original guideline document).

b. Systemic Considerations

Other indications for caution include the patient's inability to manipulate and care for contact lenses appropriately or to return for appropriate professional supervision. Contact lens wear should be approached cautiously with the patient who has immunosuppressive disease (e.g., AIDS), rheumatoid arthritis, or diabetes, which may lead to insufficient lacrimation or increased risk for corneal neovascularization and infections.

c. Noncompliant Patients

Clinicians should exercise caution, and occasionally exercise restraint, when considering contact lens fitting for patients known or suspected to be so noncompliant with appropriate contact lens care and general hygiene as to place themselves at increased risk for severe complications (See Section E "Management of Complications Associated with Contact Lens Wear," Item 1, "General Considerations," below).

3. Types of Contact Lenses

a. Hydrogel Lenses

Spherical hydrogel contact lenses are indicated for the correction of myopia and hyperopia when astigmatism is limited to less than 1.00 diopter and tears are sufficient. Toric hydrogel lenses are indicated for patients who are otherwise good candidates for hydrogel contact lenses and who wish to use contact lenses for cosmetic correction of refractive error, including visually significant astigmatism (usually greater than 0.75 diopters).

b. Rigid Lenses

Usually provide better visual results than do hydrogel contact lenses in situations of either regular or irregular astigmatism of the corneal surface. Polymethyl methacrylate (PMMA) contact lenses are occasionally useful, although the clinician must recognize that this material has virtually no oxygen permeability and that corneal metabolism is totally dependent on tear exchange when contact lenses made of this material are worn. Concern about hypoxia in patients with corneal grafts or previous superficial pannus, possibly from the use of hydrogel contact lenses of optical powers in excess of -10.00 diopters, is an indication for the use of rigid gas permeable lenses. Clinicians should note that the use of rigid contact lenses may be less successful in dusty environments.

Scleral or haptic high-Dk (oxygen permeability) rigid gas permeable (or even polymethyl methacrylate) contact lenses can be used in the management of keratoconus or other therapeutic cases such as ocular cicatricial pemphigoid or Stevens-Johnson Syndrome.

c. Hybrid and Silicone Lenses

Though not in common use, such lenses are extremely helpful in rare cases of regular or irregular corneal astigmatism (including keratoconus) or aphakia.

- 4. See the original guideline for a detailed description of these types of contact lenses.
- B. Contact Lens Examination and Fitting

The initial procedures in determining a contact lens prescription include a comprehensive eye examination to arrive at optimum refractive correction and the elimination of concerns for concurrent ocular and systemic disease.* The clinician should obtain a baseline quantification of corneal curvature ("K" values come from keratometry or videokeratography/topography measurements, and "on K" refers to the value of the flat corneal meridian). The anterior segment and tear layer should be carefully evaluated, and all pre-fitting abnormalities of the ocular and lid surfaces (e.g., corneal scars and neovascularization, blepharitis or meibomian gland dysfunction, and palpebral conjunctival follicles or papillae) should be documented, considered, and treated, when appropriate.

*Note: Refer to the Optometric Clinical Practice Guideline for the Comprehensive Adult Eye and Vision Examination (St. Louis [MO]: American Optometric Association [AOA]; 1994. 16 p. [Optometric clinical practice guideline; no. 1]).

1. Fitting Different Types of Contact Lenses

The clinician's goal is to design a contact lens from a physiologically adequate material that will have minimal mechanical impact on the corneal surface while providing the required optical correction.

Although not all clinicians always use a diagnostic evaluation of trial lenses prior to ordering the contact lens, such a process, while both somewhat labor- and time-intensive, allows clinicians and patients to gain a better perspective on the anticipated performance, including both optical and physical/physiological tolerance, of the contact lenses ordered. Some clinicians employ topical corneal anesthesia to ease initial rigid gas permeable fitting in the office. Carefully applied, this technique may be useful during the initial fitting or instruction phase of contact lens care without giving the patient a false sense of tolerance. To avoid complications of abuse, topical anesthetics should not be prescribed or dispensed to a patient.

See the original guideline document for more specific information on fitting of the following types of contact lenses:

- Spherical Hydrogel Lenses
- Toric Hydrogel Lenses
- Spherical Rigid Lenses
- Toric Rigid Lenses

2. Determination of Optical Power

Over-refraction of diagnostic or initial rigid gas permeable or hydrogel contact lenses in situ, as well as consideration of binocular vision requirements, allows the clinician to optimize contact lens optical power. Vertex distance must be considered if the over-refraction suggests the need for change greater than +/-4.00 diopters. Caution should be exercised in prescribing contact lenses for prepresbyopic myopic patients because the change in vertex distance results in a need for increased accommodation and convergence for near vision,

often resulting in symptoms of blurred vision or ocular discomfort. The opposite effect (i.e., decreased need for accommodation and convergence) may be anticipated in fitting prepresbyopic hyperopic patients with contact lenses. Contact lens power may also be calculated without an over-refraction by taking into account both the vertex distance of the manifest refraction and potential lacrimal lens power.

3. Special Design Features

The following additional design features may be required to optimize contact lens fit.

- . Lenticular Edge Modification
- a. Prism and Truncation
- b. Fenestrations
- c. Blending

See the original guideline document for specific details regarding special design features.

4. Special Concerns

See the original guideline document for additional discussion of special concerns regarding presbyopic correction, the use of contact lenses when eyes are "dry," and extended wear.

C. Dispensing Lenses and Patient Education

Contact lenses should be free from defects such as scratches, chips, or tears. Prior to initial dispensing of contact lenses, the clinician should verify that all parameters of the lenses are as ordered and that they meet established standards, such as those of the American National Standards Institute (ANSI). When appropriate, the clinician or staff should also confirm the performance of the contact lenses on the patient's eyes, optically, mechanically, and physiologically.

The patient, or a parent or guardian, should be trained in lens care, maintenance, and handling. The importance of proper hygiene, compliance with contact lens care techniques, and appropriate follow-up under professional supervision should be stressed. Warnings, precautions, and directions for use of a contact lens are found in the patient information booklet available upon request from the lens manufacturer. Information directed to the eye care practitioner is found in the package insert or in the professional fitting guide. Other extensive literature on the proper care of contact lenses is available.

The patient should be taught to perform the following steps in the care and handling of a contact lens:

Wash hands.

- Clean each contact lens by gently rubbing and thoroughly rinsing with an appropriate solution.
- Store and disinfect contact lenses in fresh appropriate solution for an appropriate time interval in a clean case until reinsertion in the eyes.
- Reclean and resoak contact lenses periodically and again preceding wear if there is an interruption in contact lens wear for any reason.

Discussion of these procedures and warnings should be provided in writing and documented in the patient's record. Professional follow-up care should be scheduled.

D. Progress Evaluations

Follow-up visits are important for proper management of the patient with contact lenses. Planned evaluation should occur during the initial weeks and months of contact lens wear to allow any necessary mechanical or optical refinements in lens prescription(s), to monitor adaptation and minimize ocular complications, and to reinforce appropriate contact lens care. Subsequent evaluations are usually indicated at 6 to 12 month intervals for healthy patients wearing cosmetic contact lenses. It is advisable to see patients who may be at additional risk for ocular compromise during contact lens wear more often than every 6 months, perhaps every 3 or 4 months or even more frequently. Such patients include those using contact lenses for extended wear, those wearing contact lenses for treatment of eye disease (e.g., keratoconus), or following corneal trauma or surgery, and children wearing contact lenses for the prevention or treatment of myopia or for correction of aphakia, for example.

The clinician should recommend additional visits whenever the contact lens patient experiences an unexpected problem in vision or ocular condition. Emergency services should be available 24 hours a day, every day of the year, through the practitioner's practice or through eye care, health care, or emergency room facilities.

Progress evaluations, planned or unplanned, should follow the "SOAP" format. The clinician should begin by obtaining a Subjective history of both contact lens wear and other concerns. The clinician should then evaluate Objective clinical findings, such as visual acuities and over-refraction results. Appropriate confrontation tests and gross observation of the eyes and adnexa should be performed at this time, followed by biomicroscopic evaluation of the lenses on the eyes and of the patient's anterior ocular segments, often with the assistance of diagnostic dyes. The clinician should periodically evaluate the corneal surface by keratometry or videokeratography/topography. Additional examinations and investigations may also be indicated. For example, a contact lens-wearing patient who complains of a sudden onset of "floaters" in one eye should be seen immediately to evaluate for possible retinal detachment. In cases of reduced vision that cannot be attributed to lens power or contact lens optical quality, ocular media and retinal assessments are indicated. The clinician can then effectively Assess the situation and Plan appropriate management steps. The clinician should monitor refraction and general ophthalmic health at whatever normal schedule is appropriate for the patient's situation.

During progress evaluations of rigid gas permeable wearers, the prescribed parameters of the contact lenses should be periodically verified and the lenses reconditioned (polished) to reduce both soilage and scratches when necessary. When contact lenses are found to have been damaged or changed during use (e.g., any cracks or edge chips, and/or warpage or flattening/steepening of the back central optical radius greater than 0.1 mm), replacement of the contact lens is advised.

E. Management of Complications Associated with Contact Lens Wear

The first step in proper management of the contact lens wearer who experiences complications is correct diagnosis. The second step is clinical grading of the severity of an observed complication or response to contact lens use. After accurate diagnosis and grading (see Table 1, below), appropriate management and clinical supervision can be provided.

Table 1. Clinical Grading of Response to Contact Lens Wear: Proposed Interpretation and Clinical Approach

Grade*	Interpretation	Clinical Approach Advised
0	Normal: no tissue changes observed	No action required; routine clinical progress evaluation suggested.
1 (minimal)	Trace: minimal if any tissue changes	Minimal, if any, change in contact lens wear/care suggested; observation encouraged.
2 (mild)	Definite tissue changes observed	Initiate clinical measures to address complication; observe clinical response.
3 (moderate)	Modest tissue changes observed; ocular damage possible	Decrease or discontinue contact lens wear and treat complication; restart contact lens wear with appropriate changes in wear/care when complication successfully reversed. Provide professional supervision.
4 (severe)	Ocular damage probable	Discontinue contact lens wear and treat complication appropriately; consider risk/benefit ratio of restarting contact lens wear

	in the future.
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Note: This is an ordinal and not integer scale.

* Ordinal scaling implies that a Grade 3 response is greater than a Grade 2; however, the interval between Grades 1 and 2 may not be the same as the interval between Grades 2 and 3.

0. General Considerations

The most effective way to address the complications of contact lens wear is to prevent them from occurring. One method of precluding many complications is to maintain contact lens care and hygiene, consistent with both common sense and U.S. Food and Drug Administration (FDA)-approved manufacturers' guidelines. Achieving and maintaining total patient compliance with recommended contact lens care, however, is often difficult.

Contact lens soilage or solution reactions, and their secondary complications, can be avoided by use of "disposable" contact lenses. These hydrogel lenses are manufactured through molding technology that maintains high-quality design standards and has reduced the cost of lenses to the extent that daily replacement of lenses has become a practical option for some patients. Prescribing disposable contact lenses has the advantage of maximizing patient convenience while minimizing the possibility of solution reactions. Rigid gas permeable contact lenses can usually be reconditioned by polishing and cleaning, but they sometimes become warped, scratched, or soiled to an extent that is beyond office rehabilitation.

Most complications of contact lens wear increase in both prevalence and severity when patients wear them on an extended or continuous basis. Therefore, restricting contact lens use to daily wear whenever possible is a means of minimizing the occurrence of these complications.

Many of the complications of contact lens wear are also accompanied, and in some cases at least partially caused, by lid diseases such as blepharitis, meibomian gland dysfunction, and dry eye. Treatment of underlying lid disease and dry eye by improving lid hygiene, the use of artificial tear drops (often in unpreserved unit doses), punctal occlusion, and appropriate antibiotic treatment, either locally or systemically, is helpful in minimizing many of the complications of contact lens wear.

Many of the complications of contact lens wear can be treated effectively by temporary discontinuation of contact lens wear. Reversal of inflammatory lid and conjunctival reactions and solution sensitivities, collapse of mild forms of corneal neovascularization, and healing of corneal epitheliopathies often occur without additional treatment. The use of adjunctive medical therapy, consisting of

artificial tears, nonsteroidal anti-inflammatory drugs (NSAIDs), mast cell stabilizers, antibiotics, and occasionally even steroid drops, should be considered.

Special precautions should be taken to avoid the spread of infection from one patient to another in the practitioner's office. These measures should include appropriate cleaning and the disinfection of diagnostic contact lenses and adjunctive equipment, especially tonometers. Disinfection must be performed by a method approved by the U.S. Centers for Disease Control and Prevention (CDC).

1. Noninfectious Complications

By far, the most prevalent complications of contact lens wear are associated with lens care and solutions and contact lens spoilage, particularly in the case of hydrogel lenses (See Table 6 in the original guideline).

Another common complication of contact lens wear is hypoxia, which induces changes at all corneal layers. These changes include microcysts and microcystic edema (MCE); central circular clouding (CCC); pseudodendritic edematous corneal formations (ECF); decreased epithelial mitosis, sensitivity and adhesion; changes in stromal thickness, acidosis, and striae; and endothelial blebs and polymegethism. In a postulated corneal exhaustion syndrome (CES), previously successful long-term contact lens wearers suddenly become intolerant of additional contact lens wear.

Superficial corneal pannus is associated with either chronic hypoxia or chronic 3/9 epithelial desiccation (rigid contact lenses). Secondary intracorneal hemorrhages can occur. Deep stromal neovascularization is a very rare complication.

Contact lens wear can lead to distortion and warpage of the corneal surface, which results in "spectacle blur" or a reversible loss of good spectacle acuity immediately following contact lens wear. Clinicians also often observe "dimple veil" epithelial depressions from bubbles of air trapped between contact lenses and the ocular surface.

True epithelial "staining" represents some epithelial cell layer disruption, which can progress to occasional erosions and even abrasions. Etiological factors may be obvious -- chemical trauma (e.g., solution reactions), mechanical trauma (e.g., damaged contact lenses, foreign bodies trapped between the contact lens and the eye), or superior epithelial arcuate lesion (SEAL or "epithelial splitting") -- or obscure. Some brands of contact lenses cause distinctive staining patterns without progressing. Clinicians should consider either keratoconus or Cogan's microcystic-map-dot-fingerprint dystrophy in any patient who presents with an abrasion without a clear-cut historical etiology (see Figure 1 in the Appendix to the original quideline).

Corneal infiltrates, both round and dendritic, may be signs of solution sensitivity, true corneal microbial infection, or even unrelated complications. The clinician should always be alert to the possibility of herpetic or Acanthamoeba infection masquerading as a more benign contact lens complication etiology (see Figure 2 in the Appendix to the original guideline).

Documented lid reactions include allergic responses such as giant papillary conjunctivitis (GPC) or ptosis. The conjunctiva is also subject to many types of toxic and allergic reactions, some totally and others partially, due to the use of contact lenses and their care solutions. The clinician should always be careful to consider masquerade syndromes (e.g., drug abuse or herpetic disease).

The clinical challenge is often to maintain contact lens wear in the face of five specific types of noninfectious complications, as discussed in the following paragraphs.

. Solution Reactions

The majority of these problems are cell-mediated (Gell-Coombs type IV) reactions to preservatives, but the anterior segment signs are often nonspecific. Solution reactions often present with both fine corneal staining, with or without infiltrates, and conjunctival injection and/or edema.

When the clinician suspects such a reaction, contact lens wear should be discontinued, and appropriate treatment and professional observation should be initiated. After reversal of the reaction, the clinician may initially try substituting one product or class of product for another. When this measure fails, hydrogel contact lens wearers may be fitted with daily disposable contact lenses to eliminate all solution issues. Rigid gas permeable wearers can use aerosol-packaged nonpreserved saline to rinse their lenses copiously prior to insertion. For fear of an Acanthamoeba infection, the use of tap water or fresh water rinses is discouraged. If water is utilized for rinsing rigid gas permeables, an additional rinse with sterile saline or conditioning solution is recommended (see Figure 3 in the Appendix to the original guideline).

a. Hypoxia

In the mid-1970s, all rigid contact lenses were made of non-oxygen-permeable polymethyl methacrylate, and early hydrogel lenses all had modest oxygen transmissibility. Hypoxia was a common complication. Most of the rigid gas permeable and hydrogel contact lenses now available, however, generally do not cause corneal hypoxia under daily wear conditions.

When there is clear evidence of hypoxic corneal changes (e.g., epithelial or stromal edema, corneal pannus greater than

approximately 2 mm unrelated to 3/9 stain), conjunctival changes, or suspected corneal exhaustion syndrome, the clinician should adjust the contact lens wear schedule or change the contact lens material or design to enhance the availability of oxygen to the anterior corneal surface (see Figure 4 in the Appendix to the original guideline).

b. Three O'clock and Nine O'clock Staining

Perhaps the most common complication of rigid gas permeable wear is 3/9 staining. Even moderate to severe 3/9 staining deserves attention to decrease the potential for this complication to advance to infection, dellen, or pseudopterygium/vascularized limbal keratitis (VLK). The principal cause of 3/9 staining is low-riding rigid gas permeable contact lenses. Therefore, an effort should be made to optimize the position of the contact lens by increasing its total diameter and/or flattening its back central optical radius. For cases of substantial corneal astigmatism, bitoric rigid gas permeable designs may be considered. When the contact lens centers well, the clinician should consider modifying the edge lift associated with the peripheral curve design, the edge thickness, and/or the total diameter. The clinician should also consider whether contact lens binding is playing a role in the development of this corneal epitheliopathy.

The condition of the patient's lids/meibomian glands and tear layers often contributes to 3/9 staining and should also be addressed (as discussed previously). Lens position and wearing time should be managed. When all attempts to solve the problem with rigid gas permeables are unsuccessful, and when there are no contraindications, the prescription of hydrogel contact lenses may also be considered (see Figure 5 in the Appendix to the original guideline).

c. Corneal Abrasion

Corneal epithelial abrasion is a common occurrence among contact lens wearers.

Treatment consists of first ruling out infection and temporarily discontinuing contact lens wear. Some clinicians believe in prophylactic antibiotic treatment, while others prefer to withhold antibiotics unless infection is suspected or proven. To decrease the risk of precipitating or enhancing a microbial corneal infection, the clinician should neither patch nor use topical steroids to treat a contact lens-associated abrasion (see Section 3a "Infectious Complications--Bacterial Infections," below). Close professional supervision is prudent until the epithelial defect has closed and the etiology of the abrasion should be considered before contact lens wear is resumed. For example, when the cause of the abrasion appears to be the

patient's failure to insert or remove the contact lenses properly, reinstruction in these procedures should precede contact lens redispensing. Management of the patient with repeated apical corneal abrasions, in particular the patient with keratoconus, may require refitting of the contact lenses with steeper back central optical radius or the use of piggyback contact lens systems (see Figure 6 in the Appendix to the original guideline).

d. Giant Papillary Conjunctivitis

Giant papillary conjunctivitis has been shown to be a Gell-Coombs type I hypersensitivity reaction. Type I reactions imply that conjunctival mast cells, presensitized by immunoglobulin E (IgE) generated by a previous encounter, are activated by a second antigen presentation. The giant papillary conjunctivitis antigen has never been identified but is understood to be related to either biological debris adherent to the surface of a contact lens or perhaps to mechanical conjunctival irritation from the edge of the contact lens itself.

If at all possible, the patient diagnosed with giant papillary conjunctivitis should first discontinue contact lens wear until he or she is symptom (itching) free and the signs (mucus, inflammatory tarsal conjunctival papillae) are subsiding. Contact lens wear may then be resumed cautiously, with improved contact lens cleaning (e.g., more frequent, increased use of enzyme cleaner). The use of peroxide disinfection or daily-disposable contact lenses is helpful for hydrogel wearers. Often it is also helpful to change the contact lens design from hydrogel to rigid gas permeable or vice-versa, or at least the edge design. Finally, topical mast cell-stabilizing agents, nonsteroidal anti-inflammatory drugs, antihistamines, and occasionally steroids (with caution to minimize the risk of secondary ocular infection, glaucoma, or cataract) may be prescribed adjunctively for those patients who on maximal nonmedical treatment still show signs or symptoms and for whom contact lens wear cannot be discontinued (e.g., those with keratoconus) (see Figure 7 in the Appendix to the original quideline).

2. Infectious Complications

Corneal microbial infection, which has an incidence of about 21 of every 10,000 people using contact lenses for extended-wear and about 4 per 10,000 people using contact lenses for daily-wear per year, is probably the contact lens-associated complication of most concern to both patients and practitioners. Microbial corneal infections are identified by the symptoms of ocular pain and photophobia and by the observation of clinical signs such as corneal epithelial defects in association with underlying inflammatory infiltration, often accompanied by anterior chamber reaction (including hypopyon in

some cases), conjunctival discharge, lid swelling, and conjunctival injection.

Corneal infection is a potentially blinding disease, but fortunately, it is rarely encountered when the use of contact lenses is restricted to daily wear with good care and hygiene. When suspected or diagnosed, such lesions deserve immediate aggressive treatment and management. Whenever any of the signs or symptoms of corneal infection occur, contact lens wear should be discontinued in both eyes to decrease the potential for bilateral disease.

. Bacterial Infections

Corneal infections associated with contact lens wear are usually bacterial, primarily attributable to the Gram-negative Pseudomonas aeruginosa, but also commonly due to Grampositive Staphylococcus aureus and Staphylococcus epidermidis. Other bacteria are also occasionally cultured from such lesions. Bacterial corneal infection has been primarily associated with wearing contact lenses through one or more sleep cycles (extended or continuous wear).

Poor compliance with appropriate contact lens care procedures also appears to be a major risk factor for microbial infection (especially Acanthamoeba, as discussed in the next section).

Traditional management of corneal ulcers and severe infections begins with the acquisition of cultures on blood and chocolate agars, on Sabouraud's medium (for fungi), or on thioglycolate medium (for anaerobes), with Gram-staining of smears for microscopic evaluation. A sterilized Kimura spatula is used to acquire material for these laboratory investigations by scraping the leading edge of the corneal ulcer. Aggressive topical treatment should begin with dual therapy: specially prepared fortified topical aminoglycosides (e.g., gentamicin, tobramycin, amikacin) to attack Gram-negative bacteria and cephalosporins (e.g., cefazolin) or vancomycin to destroy Gram-positive bacteria. Treatment may be modified by observation of the patient's clinical course and the laboratory identification of likely microorganisms and their antibiotic sensitivities. Adjunctive patching and early steroid treatment are usually contraindicated.

Topical fluoroquinolone antibiotics (e.g., ciprofloxacin, ofloxacin) were introduced into ophthalmic care in the early 1990s and initiated treatment evolution. Several studies discussed the clinically successful use of 0.3% commercial-strength topical fluoroquinolone antibiotics as monotherapy for suspected bacterial corneal infections without cultures, especially when the lesions were relatively small (<2 mm), and neither central nor deep. Many clinicians found fluoroquinolone

monotherapy to be as effective as fortified dual therapy, and initial cultures were believed unnecessary in many cases.

Emerging resistance to the fluoroquinolone antibiotics has been a theoretical concern, however, and recently was reported. Some clinicians are now discussing a new form of dual therapy, utilizing both fluoroquinolone and cephalosporin agents, for example. Treatment of bacterial corneal infection therefore remains an area of some controversy and of evolving strategies, and clinicians are advised to maintain vigilance.

a. Acanthamoeba Infections

The clinician should always consider the possibility of Acanthamoeba species infections in any contact lens-related keratitis, especially in cases of chronic disease with initially negative culture results and failure to respond to antibiotic therapy. Clinical suspicion should be increased when the patient reports extreme ocular pain and/or a history of exposing the contact lenses to nonsterile water, or when an unusual epitheliopathy (reminiscent of herpetic epithelial disease) or peripheral corneal radial neuropathy is observed. Special culture techniques are available for Acanthamoeba infections, but tissue biopsy is often necessary.

Combinations of the following four types of pharmacological agents have been used successfully for medical treatment of Acanthamoeba keratitis:

- Antibiotic/aminoglycoside: paromomycin, neomycin
- Antifungal: clotrimazole, ketoconazole, itraconazole, miconozole, fluconazole
- Antiparasitic/aromatic diamidine: propamidine isethionate, hydroxystibamidine, hexamidine diisethionate
- Biocide/cationic antiseptic: polyhexamethylene biguanide, chlorhexidine gluconate, povidone-iodine

Misdiagnosis and medical failures in the treatment of Acanthamoeba infections are common.

b. Fungal Infections

Fungal corneal infections are extremely rare among cosmetic contact lens wearers. Antifungal pharmaceutical agents (both commercial and custom-made) are available, but medical treatment is often quite difficult and prone to failure. It is important to note that atypical mycobacterium and Acanthamoeba infections often mimic fungal corneal ulcers and vice-versa.

c. Viral Infections

Concomitant viral corneal infections, of which adenovirus and herpes simplex virus are of principal concern, can occur during contact lens wear. No causative association has been uncovered for such viral infections, but contact lens wear should be discontinued during viral infections unless the contact lens is being used in a treatment protocol. Adenovirus infection is usually successfully managed by supportive therapy such as tear supplements and topical decongestants or by steroid therapy, as the clinical condition indicates. Effective antiviral agents are available for the treatment of herpetic eye disease. The clinician who observes an apparent herpetic keratitis in association with use of contact lenses, however, should always consider the possibility of Acanthamoeba as an alternative infectious agent.

It is prudent to consider discarding contact lenses that have been worn during the period of viral infection and dispense new contact lenses once the infection has resolved. Otherwise, some effort should be made to disinfect contact lenses, perhaps by soaking them in an appropriate disinfecting solution (e.g., contact lens-grade 3% hydrogen peroxide) for 10-15 minutes.

More aggressive medical treatment, including subconjunctival injections and/or systemic antibiotic treatment, hospitalization, and perhaps corneal transplantation, may be necessary, especially in cases of indolent, refractory, or non-bacterial corneal infections. The referral of patients with severe inflammatory or infectious ocular disease to a specialist in corneal and external eye diseases is prudent.

CLINICAL ALGORITHM(S)

Algorithms are provided for the management of:

- Corneal stain
- Corneal infiltrates
- Conjunctival injection (conjunctivitis)
- Contact lens induced acute and chronic corneal hypoxia
- "3-9" or juxtapositional corneal stain
- Corneal abrasion
- Giant papillary conjunctivitis (GPC)

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Individuals with refractive error seek improved visual acuity to enhance their perception and enjoyment of the world. Contact lenses are one alternative for vision correction. Enhanced materials and designs have made contact lenses a practical option for the majority of patients who are motivated to use them.

Additional benefits include:

- Improved care of patients wearing contact lenses
- Improved management of complications encountered during contact lens wear

POTENTIAL HARMS

- The majority of complications encountered with daily wear contact lenses are manageable by discontinuing their use. Inconvenience, minor physiological and allergic problems, and interruptions in wear are commonplace.
- Noninfectious complications include solution reactions, hypoxia, three o'clock and nine o'clock staining, corneal abrasions, and giant papillary conjunctivitis. Infectious complications include bacterial, Acanthamoeba, fungal, or viral infections.
- More severe (i.e., vision-threatening) complications are less common and include corneal microbial infection and extreme forms of corneal neovascularization, which can lead to scarring of the cornea in the area of the visual axis.

Subgroups Most Likely to be Harmed:

- Patients who extend contact lens wear, especially through one or more sleep cycles.
- Patients who do not comply with proper hygiene and contact lens cleaning and care.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Clinicians should not rely on this Clinical Guideline alone for patient care and management. Please refer to the references and other sources listed in the original guideline for a more detailed analysis and discussion of research and patient care information.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Staying Healthy

IOM DOMAIN

Effectiveness Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Optometric Association. Care of the contact lens patient. St. Louis (MO): American Optometric Association; 2000 Jan 1. 77 p. (Optometric clinical practice guideline; no. 19). [178 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000

GUI DELI NE DEVELOPER(S)

American Optometric Association - Professional Association

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American Optometric Association Consensus Panel on the Care of the Contact Lens Patient

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

According to the guideline developer, this guideline has been reviewed on a biannual basis and is considered to be current. This review process involves updated literature searches of electronic databases and expert panel review of new evidence that has emerged since the original publication date.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the <u>American Optometric Association (AOA) Web site</u>.

Print copies: Available for purchase from the American Optometric Association (AOA), Order Department, 243 North Lindbergh Boulevard, St. Louis, MO 63141; Telephone (800) 262-2210 (U.S. only).

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on March 1, 2001. It was verified by the guideline developer as of May 16, 2001. This summary was most recently updated on May 3, 2005 following the withdrawal of Bextra (valdecoxib) from the market and the release of heightened warnings for Celebrex (celecoxib) and other nonselective nonsteroidal anti-inflammatory drugs (NSAIDs).

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